



FedEx Regulatory Alerts & Updates

Regulatory Alert: FDA Import Requirements for Personal Protective Equipment

March 31, 2020

BACKGROUND INFORMATION

The U.S. Food and Drug Administration (FDA) has provided instruction to the import community via CSMS messages #42124872 and #42168200 regarding the submission of FDA entry information for certain personal protective equipment (PPE) and other devices. Following the FDA's instructions will help facilitate the import process for products related to the Coronavirus Disease 2019 (COVID-19) public health emergency.

Note: The circumstances surrounding the COVID-19 public health emergency are very fluid and subject to rapid changes.

WHAT HAS CHANGED?

In the CSMS messages issued in late March 2020, the FDA laid out instructions for three different categories of personal protective equipment.

The first type is PPE designed for general purpose or industrial use (masks, respirators, gloves, etc.) that are not regulated by the FDA. For these types of goods, FDA data elements such as the manufacturer's name and address are not required to be provided on the commercial invoice.

Examples of these general purpose products that the FDA does not regulate are:

- Respirators purchased at a hardware store for use while completing a construction project
- Latex gloves purchased at an auto parts store to be used while changing your car oil
- 3-ply disposable face masks for household use (such as when cleaning or dusting)

The second type is PPE products used for the prevention of illness or disease that are authorized for emergency use pursuant to an Emergency Use Authorization (EUA). These products are designated by FDA Intended Use Code 940.000: Compassionate Use/Emergency Use Device.

Below is a list of some products and their FDA product codes that are currently authorized by an EUA. A full list is included in the References section.

- Diagnostic tests with product codes: 83QPK, 83QKO, 83QJR
- Masks/respirators with product code: 80NZJ

Goods classified within these FDA product codes require FDA clearance, but the EUA designation allows for more relaxed requirements.

Note: The manufacturer's name and address will need to be included on the commercial invoice along with the FDA product code, but submission of the typically required FDA Affirmation of Compliance codes is optional.

Questions regarding appropriate product coding can be submitted to FDA at:

COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Manufacturers and other stakeholders may submit a request to FDA in order to have their products added to the EUA. If you have questions, please email CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

The third type are products regulated by FDA as devices, not authorized by an EUA, but where an enforcement discretion policy has been published in a guidance document. These products are designated by the FDA intended use code 081.006. Currently, the only products that fall into this category are:

- Face masks and respirators
- Non-invasive remote monitoring devices
- Ventilators, their accessories and other respiratory devices
- Diagnostic tests

Similar to the goods covered by an EUA, the products covered under 081.006 will require the manufacturer's details and the FDA product code, but the submission of the typically required FDA Affirmation of Compliance codes is optional.

The FDA has provided guidance documents for each of these types of products (links included in the References section below), and those documents contain the product codes that fall within the scope of each guidance.

Q&A

Q1: How can I tell the difference between FDA-regulated PPE and PPE that the FDA does not regulate?

A1: The determining factor in whether or not the FDA regulates PPE is its intended use. If the products are intended to prevent, mitigate or treat a disease or illness, then the FDA regulates those products. If the intended use is for general purpose protection or industrial use (products that are not intended to prevent disease or illness), then they are not regulated by FDA.

A clear description that shows the intended use of the goods is of utmost importance. For example, if latex gloves are being imported for general purpose use such as to keep paint off of a person's hands when painting, then a good description would be "latex gloves for household use." If N95 respirators are being imported for use by medical personnel, then a good description would be "N95 respirators for use by medical personnel."

Q2: What is an FDA Affirmation of Compliance code?

A2: To help expedite FDA's review of product compliance, the entry filer submits information at the time of entry, such as registration, listing and approval numbers. This information is submitted by using Affirmation of Compliance codes. The FDA provides an overview of Affirmation of Compliance codes on its website (link in the References section below).

Q3: What are the FDA data requirements for PPE such as masks, respirators, gowns and gloves?

A3: For PPE not authorized for emergency use pursuant to an EUA, it is important to provide the appropriate FDA data elements with each shipment so that the broker can submit the entry to the FDA in a timely and efficient manner. The majority of PPE are regulated as class I or class II medical devices. Included in the References section is a link to the FDA PPE web page that provides more information.

Here is an example of the FDA Affirmation of Compliance codes required for a foreign-manufactured class II medical device:

- FDA Intended Use Code
- LST – Device Listing number (provided by the FDA to the manufacturer at time of device registration)
- PMN – 510(K) number
- DFE – Device Foreign Exporter (this is the shipper's FDA registration number)
- DEV – Device Manufacturer (manufacturer's FDA registration number)

More information regarding how to register with the FDA provided in the References section below.

Note: For every shipment of FDA-regulated medical devices, regardless of whether they have been authorized for emergency use, the FDA product code, a description of the intended use, and the manufacturer's name and address will be required.

Q4: How do I find my medical device's FDA product code?

A4: The FDA has a web page dedicated to product code classification which provides information about how to find a product code. A link to this site is provided in the References section.

Further questions regarding appropriate product coding or intended use can be submitted to FDA at: COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

REFERENCES:

CSMS message #42124872:

https://content.govdelivery.com/bulletins/gd/USDHSCBP-282c648?wgt_ref=USDHSCBP_WIDGET_2%3Futm_source%3Dsearch.usa.gov&utm_medium=search.usa.gov&utm_term=undefined&utm_content=undefined&utm_campaign=%28not+set%29&gclid=undefined&dclid=undefined&GAID=102834089.1540533732

CSMS message #42168200:

<https://content.govdelivery.com/accounts/USDHSCBP/bulletins/2836f88>

FDA supplemental guide (v2.5.1):

<https://www.cbp.gov/sites/default/files/assets/documents/2020-Mar/FDA%20Supplemental%20Guide%20Release%202.5.1%202018%200410.pdf>

Full list of Emergency Use Authorizations (EUAs) currently in place:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19>

FDA guidance for face masks and respirators:

<https://www.fda.gov/media/136449/download>

FDA guidance for non-invasive remote monitoring devices:

<https://www.fda.gov/media/136290/download>

FDA guidance for ventilators, their accessories and other respiratory devices:

<https://www.fda.gov/media/136318/download>

FDA guidance for diagnostic tests:

<https://www.fda.gov/media/135659/download>

FDA Affirmation of Compliance code overview:

<https://www.fda.gov/industry/entry-submission-process/affirmation-compliance-codes>

FDA Personal Protective Equipment (PPE) web page:

<https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control>

FDA web page regarding medical device registration:

<https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>

FDA Product Code Finder web page:

<https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database>